

REMARKS

Claims 1-6 are pending. Claims 1, 3 and 4 have been amended. Support for the amendment to claim 1 can be found in paragraphs [0017] and [0019] of the specification. No new matter has been added by way of this amendment. Reconsideration of this application as amended is respectfully requested.

REJECTION UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

Claims 3 and 4 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. Claim 3 has been amended to include "compound" after "platinum." Claim 4 has been amended to delete the recitation "to complete solution." Withdrawal of the rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 102(b)

Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. § 102(b), as anticipated by U.S. Patent 6,287,593 [the "'593 patent"]. Applicants respectfully traverse this rejection.

Amended claim 1 is directed to solid lipid nanoparticles of a platinum complex comprising a platinum compound *dissolved in an aqueous solution*. The '593 patent does not teach solid lipid nanoparticles that comprise a platinum compound dissolved in an aqueous solution. Rather it teaches a lipid complex comprising a water-insoluble platinum compound, more specifically, a lipid or liposome complex of a phospholipid and a water-insoluble platinum dicarboxylate. See columns 1-2. Thus, the '593 patent does not teach the claimed invention.

In view of the above, withdrawal of this rejection is respectfully requested.

REJECTION UNDER 35 U.S.C. § 103(a)

Claim 2 is rejected under 35 U.S.C. § 103(a) as being obvious over the '593 patent in view of U.S. Patent 6,596,889 [the "'889 patent"] or U.S. Patent 6,011,166 [the "'166 patent"]. Applicants respectfully traverse this rejection.

The '593 patent, which is the primary reference relied upon by the Examiner, teaches lipid complexes comprising water-insoluble platinum dicarboxylate. The '593 patent neither teaches nor suggests solid lipid nanoparticles comprising a platinum compound dissolved in an aqueous solution. A person of ordinary skill in the art would not have found any rationale based on the '593 patent alone or taken with any of the secondary references to produce the claimed invention.

As stated in column 1, lines 15-33 of the '593 patent: "Several platinum complexes have shown excellent activity against cancer. The clinical use of such complexes has been severely limited by the insolubility of the complexes in pharmaceutically acceptable vehicles. For example, diaminocyclohexane (DACH) complexes with platinum compounds have been shown to be active against several types of cancer. However, the DACH-Pt complexes are quite insoluble in aqueous vehicles and many organic solvents. The insolubility of the DACH-Pt in organic solvents has precluded their encapsulation in liposomes or their use in lipid complexes by known methods." The focus of the invention disclosed in the '593 patent is thus quite clear – namely formulating DACH and other water-insoluble complexes. The invention taught in the '593 patent is directed to lipid complexes and liposomes of highly water insoluble platinum complexes that are made by simultaneously reacting a DACH-platinum nitrate with a phospholipids in a chloroform/ethanol solution and a carboxylic acid to form the lipid complex. See, column 1, lines 55-65. The patentees go on to explain their discovery that the carboxylation of a platinum

compound "greatly reduces its water solubility," and by postponing carboxylation until formation of the lipid complex or liposome, the solubility of the platinum entity is maintained so that a solution of the complex is available for formation of the lipid complex or liposome.

The secondary references fail to cure the deficiencies of the '593 patent. By the Examiner's own admission, they teach water-soluble platinum complexes. Moreover, the '593 patent emphasizes that "those skilled in the art will appreciate that the methods taught herein are also applicable to the preparation of lipid complexes or liposomes and lyophilizates of other platinum complexes which are considered water-insoluble and cannot be administered by injection or infusion." See column 1, lines 46-50. A person of ordinary skill in the art simply would not have modified the inventive formulations taught in the '593 patent in the manner alleged by the Examiner. See *Life Technologies Inc. v. Clontech Lab, Inc.*, 224 F.3d 1320, 1325, 56 U.S.P.Q.2d 1186, 1190 (Fed. Cir. 2000) (quoting *Standard Oil Co. v. American Cyanamid Co.*, 774 F.2d 448, 454, 227 U.S.P.Q. 293, 297 (Fed. Cir. 1985) (which notes that unlike inventors, the person of ordinary skill is an objective legal construct presumed to think along conventional lines without undertaking to innovate, whether by systematic research or by extraordinary insights). Thus, the collective teachings of the prior art do not present any rationale by which a person of ordinary skill in the art would have substituted water-soluble platinum complexes for the water-insoluble complexes taught in the '593 patent. In any event, it would certainly appear that even if the alleged substitution were made, the resultant complex would still not contain water.

To the extent that the Examiner alleges that it would have been obvious to not only substitute a water soluble platinum for a water-insoluble platinum complex, but to substitute an aqueous medium for the lipid, Applicants traverse. Here again, the person of ordinary skill in the art would not have modified the '593 patent formulations in these ways because it would have been appreciated that they would destroy the operability of the '593 patent. A modification of references that destroys the operability of the references is not obvious. See, *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) (reversing the decision of obviousness on the ground that the proposed modification of the prior art would have rendered the claimed invention inoperable for its intended purpose).

In view of the foregoing, claim 2 would not have been obvious over the cited prior art. Accordingly, withdrawal of this rejection is respectfully requested.

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he/she might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge

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Respectfully submitted,

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